

Remarks

Claims 1 to 25 and claims 28 to 31 have been amended, claims 26 to 27 are cancelled and claims 32 to 34 have been added so that claims 1 to 25 and 28 to 34 are pending in this application of which only claim 1 is in independent form. Support for the amendment to claim 1 can be found throughout the specification, e. g., in original claim 8. Support for new claims 32 to 34 can be found, e.g., in original claim 11, on page 8, in the paragraph starting on line 25 to page 9, first paragraph and on page 15, in the paragraph starting on line 10.

On pages 2 to 4, the Office rejected claims 1 to 25 and 28 to 31 under 35 USC §103(a) as obvious over Leipner et al., 2001 (hereinafter **Leipner**) in view of U.S. Patent 6,048,846 to **Cochran** and further in view of Friedman & Sklan, 1989 and Ramussen & Seljelid, 1991)

On page 4, the Office also refers to Stauder et al. Since this reference is not further identified, applicant assumed that the Office referred to the Stauder et al. reference submitted by applicant with his Information Disclosure Statement (IDS) of October 31, 2005. If this should not be the case, applicant respectfully requests clarification.

The Office expressed the opinion that Leipner teaches therapeutic use of a composition of proteolytic enzymes comprising one or more hydrolases, papain, bromelain, trypsin, chymotrypsin as well as the flavonoid rutein p. 780, col. 2, lines 19-21) and the oral administration of this composition (p. 780, col. 1, last paragraph).

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The Office acknowledges that Leipner does not teach any of the antioxidants listed in (a) of claim 1, namely: vitamins having antioxidant activity, carotenoids, selenium containing substances and ubiquinones, any amino acid according to (b) or and polysaccharide according to (c) of claim 1.

However, referring to col. 4, lines 1 to 4 of the Cochran patent, the Office stated that Cochran teaches a composition that strengthens the bodies defense system comprising:

- one or more hormones,
- one or more amino acids,
- one or more enzymes, vitamins and antioxidants, and
- one or more minerals.

The Office further expressed the opinion that Cochran teaches coenzyme Q-10, different carotenoids, vitamins, selenium and amino acids (col. 4, lines 45-56 and Fig. 1).

On page 4, the Office reasoned that it would have been obvious to one of ordinary skill in the art to combine the teachings of Leipner, Stauder and Cochran to obtain a composition to strengthen the immune response and to treat inflammatory rheumatic disorders by combining the claimed ingredients because a composition of proteolytic enzymes comprising papain, bromelain, trypsin, chymotrypsin, flavonoids, antioxidants, amino acids, were being used in anti-inflammatory therapy and to strengthen the immune response.

The Office cited Friedman & Sklan, 1989 and Ramussen & Seljelid, 1991 for their disclosure of  $\beta$ -glucan and the weakening effects of vitamin A acetate deficiency,

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respectively.

Applicant has amended the claims to specify that the hydrolases are a combination of proteases, in particular plant/animal proteases.

These combinations of plant and/or animal proteases further include one or more of the additional components recited in (a) to (c) of claim 1.

A combination of proteases, in particular plant and animal proteases (see also claim 8 as amended), was shown to have synergistic effects, in particular, if combined with antioxidants, especially selenium-containing substances such as sodium selenite, but also when combined with flavonoid-containing substances, amino acids and/or polysaccharides (see disclosure on page 8, starting on line 25 to page 9, line 5).

In particular, a combination of proteases, such a bromelain + papain or bromelain or bromelain + papain + trypsin and/or chymotrypsin, improve through their immunomodulatory effect the immunomodulatory properties of sodium selenite (see claims 11, and new claims 33 and 34). An imbalance of the various immune system parameters can be prevented by concurrent administration of sodium selenite together with proteases as provided in the compositions of in particular claims 11, 33 and 34 (see disclosure, paragraph bridging pages 14 and 15 and the paragraph on page 15, starting on line 10).

Leipner provides an overview of the use of proteases such as bromelain, papain, trypsin and chymotrypsin and the results obtained in patients with rheumatic diseases, which are said to be inconsistent. Stauder et al. report on positive results obtained with hydrolytic enzymes as contained in, e.g., WobeMugos® (trypsin, chymotrypsin, papain)

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in combination with radiotherapy in abdominal cancer patients.

The deficiencies of Leipner have been noted by the Office and have been discussed above. Stauder does not cure these deficiencies.

U.S. Patent 6,048,846 to Cochran discloses a composition comprising a combination of at least one hormone, at least one amino acid, at least one enzyme and/or vitamin, and at least one mineral. The mixture of hormone, amino acid, enzyme and mineral are said to be balanced. The combination is reported to operate synergistically to provide both nutrients and tools for the body to use the same.

Noticeably, Cochran does not distinguish in his definition of enzymes in col. 4 (to which the Office specifically refers) between enzymes and antioxidants. Strikingly, a number of vitamins are also included in this definition of enzymes, but are, in contrast to the present invention, not categorized as antioxidants.

Cochran also does not mention specific enzymes such as hydrolases and certainly not animal/plant proteinases as presently claimed.

Cochran, which the rejection combines with Leipner and Stauder et al., lacks any reference to a combination of proteases. Beyond that, Cochran chooses a broad definition of "enzyme" (col. 4, lines 42 to 51) that does not even distinguish between enzymes in the "classical" sense and antioxidants, thereby suggesting interchangeably of enzymes in the "classical" sense such as proteases and antioxidants. Vitamins, in turn, are treated as an entity separate from antioxidants. Selenium is categorized as a mineral.

In contrast to this, the present disclosure explains that combination of proteases, in particular plant and animal proteases (which, in combination, already exceed the effect of single proteases, see page 8, lines 25 to 32) and the specified antioxidants such as "selenium containing substances" pronounce the effect of the combination of proteases (page 9, line 1 to 5). In fact, the combination of sodium selenite with such a combination of a proteases can prevent imbalances of various immune system parameters (page 14, line 36 to page 15, line 8), resulting in further synergistic effects.

Neither Leipner nor Stauder contain any reference to food products. Cochran, while realizing that at least some of the components of his composition are nutrients, also does not mention food products comprising his combination and certainly not the combination currently claimed in, e.g., claims 24, which considerably simplifies the proper administration of the composition of, e.g., claim 1.

Applicant has shown above that the combination of Leipner, Stauder et al. and Cochran does not suggest the combination as presently claimed. There is noting in Leipner, Stauder et al and Cochran "teach or fairly suggest" the composition as presently claimed. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). See also MPEP §2144.08.

To the contrary, the far reaching definition of "enzymes" provided by Cochran and discussed above, would tend to suggest to a person of skill in the art that, e.g., enzymes and antioxidants are interchangeable rather than, as discussed above, providing synergistic effects. *KSR Int'l v Teleflex*, 127 S.Ct. 1727, 1740 (S Ct. 2007).

In view of the above, applicant believes that the application is now in condition for allowance and an early issuance of a notice of allowance is earnestly solicited. The

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Office is urged to call the undersigned at the number provided below to resolve any issues that remain.

The fee for an one month extension of time as well as four additional claims is submitted herewith. No additional fee is believed to be due with this amendment. However, the Commissioner is authorized to charge the undersigned's deposit account no. 50-3135 for any fees that might be required to ensure consideration of this submission.

Respectfully submitted,

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